IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#1B

IN RE:	U.S.PATENT NO. 5,567,817
ISSUED:	OCTOBER 22, 1996
TO:	STEPHEN J. RAY AND KENNETH RICHARDSON
FOR:	TRIAZOLE ANTIFUNGAL AGENTS
FROM:	SERIAL NO. 08/432,414
OF:	MAY 1, 1995

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Commissioner for Patents
Box Patent Extension
Washington, DC 20231

Sir:

EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156

Transmitted herewith are the application papers of PFIZER INC., dated July 12, 2002, for extension of the term of U.S. Patent No. 5,567,187 under 35 U.S.C. §156, based on the regulatory review period for VFEND® (Voriconazole) Tablets, together with two duplicate copies as required under 37 C.F.R. §1.740(b) and two additional duplicate copies of the application pursuant to M.P.E.P. §2753, for a total of four copies and one original.

As set forth under 37 C.F.R. §1.20(j), please charge the sum of $1,060.00 to Deposit Account No. 16-1445 for the filing of this application for extension of patent term. Also, please charge any underpayment, or any additional fees that may be required, or credit any overpayment, to Deposit Account No. 16-1445. Two copies of this paper are enclosed.

07/17/2002 AKELLEY 00000006 161445 5567817
01 FC:111 1120.00 CH

Respectfully submitted,
PFIZER INC.

Date: July 15, 2002

By: Adrian G. Looney

Adrian G. Looney
Attorney for Applicant
Reg. No. 41,406
Tel.: (212) 733-1038
Fax.: (212) 573-1939

PFIZER INC.
Legal Division
150 East 42nd Street
New York, NY 10017-5755

Patent Application
Attorney Docket No. PC7704C
Issued as U.S. Patent No. 5,567,817

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: **U.S. PATENT NO. 5,567,817** :

ISSUED: **OCTOBER 22, 1996** :

TO: **STEPHEN J. RAY AND KENNETH RICHARDSON** :

FOR: **TRIAZOLE ANTIFUNGAL AGENTS** :

FROM: **SERIAL NO. 08/432,414** :

OF: **MAY 1, 1995** :

Commissioner for Patents
Box Patent Extension
Washington, DC 20231

Sir:

ASSOCIATE POWER OF ATTORNEY PURSUANT TO 37 C.F.R. §1.34

Please recognize:

Name of Attorney: Adrian G. Looney

Address: Pfizer Inc.
150 East 42nd Street

Reg. No.: 41,406

Tel. No.: (212)733-1038

as an associate attorney to prosecute and to transact all business in the U.S. Patent and Trademark Office connected with the above-identified patent.

Date: July 15, 2002

Respectfully submitted,

Pfizer, Inc
Patent Department, 5th floor
150 East 42nd Street
New York, NY 10017
(212) 573-4585

Bryan C. Zielinski
Attorney for Applicants
Reg. No. 34,462

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE:	U.S.PATENT NO. 5,567,817
ISSUED:	OCTOBER 22, 1996
TO:	STEPHEN J. RAY AND KENNETH RICHARDSON
FOR:	TRIAZOLE ANTIFUNGAL AGENTS
FROM:	SERIAL NO. 08/432,414
OF:	MAY 1, 1995

Commissioner for Patents
Box Patent Extension
Washington, DC 20231

Sir:

APPLICATION FOR EXTENSION OF THE TERM OF
UNITED STATES PATENT NO. 5,567,817 UNDER 35 U.S.C. §156
FOR VFEND® (VORICONAZOLE) TABLETS

Your applicant, PFIZER INC., a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, NY 10017, United States of America, represents that it is the owner of the entire right, title and interest in and to Letters Patent of the United States No. 5,567,817 granted to STEPHEN J. RAY and KENNETH RICHARDSON on the 22nd day of October, 1996, for TRIAZOLE ANTIFUNGAL AGENTS, by virtue of assignments, recorded in the United States Patent and Trademark Office (hereinafter referred to as "the Patent Office") on the 25th day of January 1991, at Reel 5580, Frame 0166.

Pursuant to the provisions of 37 C.F.R. §1.730, your applicant hereby applies for an extension of the term of Patent No. 5,567,817 under 35 U.S.C. §156 of 945 days, based on the materials set forth herein and in the accompanying papers.

In the materials which follow herein, numbered paragraphs (1) through (15) correspond to paragraphs (1) through (15) of 37 C.F.R. §1.740(a).

(1) The approved product is VFEND® (voriconazole) Tablets. VFEND® Tablets consist of voriconazole and pharmaceutically-acceptable carriers. Voriconazole is the generic name of the chemical compound which is known by the PFIZER INC. Code Number, UK-109,496, and it is further identified as follows:

(4) The active ingredient in VFEND® Tablets is voriconazole. Said active ingredient has not been previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act or the Virus-Serum-Toxin Act.

(5) This application is being submitted within the sixty day period permitted for its submission pursuant to 37 C.F.R. §1.720(f). The last day on which this application could be submitted is July 22, 2002.

(6) The patent for which an extension is being sought is identified as follows:

Inventors: STEPHEN J. RAY AND KENNETH RICHARDSON
Patent No.: 5,567,817
For: TRIAZOLE ANTIFUNGAL DERIVATIVES
Issued: OCTOBER 22, 1996
Expires: OCTOBER 22, 2013

(7) A copy of Patent No. 5,567,817, the patent for which an extension is being sought, is attached hereto as EXHIBIT A.

(8) A request for certificate of correction for Patent No. 5,567,817 was filed on June 14, 2002 and to this date has yet to be ruled on (a copy of the Request for Certificate of Correction and accompanying documents are included herewith as EXHIBIT B). One maintenance fee payment for Patent No. 5,567,817 was made to keep the patent in force beyond four years from its issue date (a copy of the receipt from such payment is included herewith as EXHIBIT C). Patent No. 5,567,817 has no disclaimers or re-examination certificates.

(9) Patent No. 5,567,817 claims the approved product, pharmaceutical compositions including the approved product, and a method of using the approved product. Claims 1 to 4 claim the approved product *per se*; claims 5 to 8 claim pharmaceutical compositions which contain the approved product and are useful for the approved use; and claims 10 to 12 claim the approved use of the approved product. A showing that lists each applicable patent claim and demonstrates the manner in which each applicable patent claim reads on the approved product, a pharmaceutical composition containing the approved product, or a method of using the approved product is as follows:

Claim 1 of Patent No. 5,567,817 reads as follows:

Chemical Name

(2R,3S)-2-(2,4-difluorophenyl)-3-(5-fluoro-4-pyrimidinyl)-1-(1*H*-1,2,4-triazol-1-yl)-2-butanol

Molecular Formula

$C_{16}H_{14}F_3N_5O$

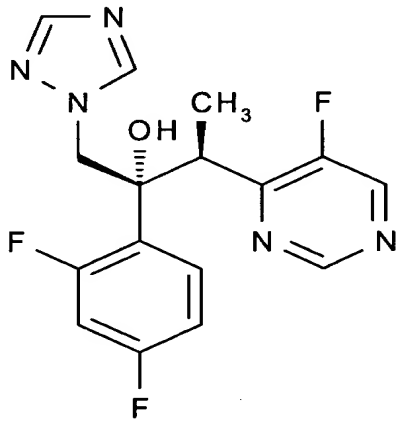
Molecular Weight

349.3

Physical Description

VFEND® Tablets contain 50 mg or 200 mg of voriconazole. Voriconazole is a white to light-colored powder. The inactive ingredients include lactose monohydrate, pregelatinized starch, croscarmellose sodium, povidone, magnesium stearate and a coating containing hydroxypropyl methylcellulose, titanium dioxide, lactose monohydrate and triacetin.

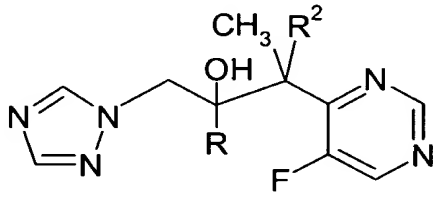
Chemical Formula



(2) VFEND® (voriconazole) Tablets was subject to regulatory review under section 505(b) of the Federal Food, Drug and Cosmetic Act, which is codified at 21 U.S.C. §355(b).

(3) VFEND® (voriconazole) Tablets received permission for commercial marketing or use under section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §355(b), on May 24, 2002. It was approved for the treatment of invasive aspergillosis and serious fungal infections caused by *Scedosporium apiospermum* and *Fusarium spp.*, including *Fusasium solani*, in patients intolerant of, or refractory to, other therapy.

"A compound of the formula

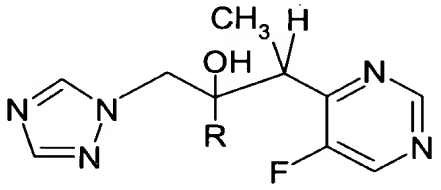


or a pharmaceutically acceptable salt thereof, wherein R is 2,4-difluorophenyl, and R^2 is hydrogen or methyl."

When R is 2,4-difluorophenyl and R^2 is H and the absolute configuration at the 2-position is R and S at the 3-position, the compound claimed is voriconazole. Therefore, claim 1 reads on the approved product.

Claim 2 of Patent No. 5,567,817 reads as follows:

"A compound of the formula



or a pharmaceutically acceptable salt thereof, wherein R is 2,4-difluorophenyl, 2,4-dichlorophenyl, 2-chlorophenyl, 4-fluorophenyl,or 2-fluorophenyl."

When R is 2,4-difluorophenyl and the absolute configuration at the 2-position is R and S at the 3-position the compound claimed is voriconazole. Therefore, claim 2 reads on the approved product.

Claim 3 of Patent No. 5,567,817 claims 2-(2,4-difluorophenyl)-3-(5-fluoropyrimidin-4-yl)-1-(1H-1,2,4-triazol-1-yl)butan-2-ol, or a pharmaceutically acceptable salt thereof, when the absolute configuration at the 2-position is R and S at the 3-position the compound claimed is voriconazole and a pharmaceutically acceptable salt of voriconazole, respectively. Therefore, claim 3 reads on the approved product.

Claim 4 of Patent No. 5,567,817 claims (2R,3S)-2-(2,4-difluorophenyl)-3-(5-fluoropyrimidin-4-yl)-1-(1H-1,2,4-triazol-1-yl)butan-2-ol, or a pharmaceutically acceptable salt thereof, which is voriconazole and a pharmaceutically acceptable

salt of voriconazole, respectively. Therefore, claim 4 reads on the approved product.

Claim 5 of Patent No. 5,567,817 claims a pharmaceutical composition for treating a fungal infection in a mammal which comprise an effective amount of the compound of claim 1 and a pharmaceutically acceptable carrier. Since claim 1 claims voriconazole claim 5 reads on a pharmaceutical composition comprising an effective amount of the approved product.

Claim 6 of Patent No. 5,567,817 claims a pharmaceutical composition for treating a fungal infection in a mammal which comprise an effective amount of the compound of claim 2 and a pharmaceutically acceptable carrier. Since claim 2 claims voriconazole claim 6 reads on a pharmaceutical composition comprising an effective amount of the approved product.

Claim 7 of Patent No. 5,567,817 claims a pharmaceutical composition for treating a fungal infection in a mammal which comprise an effective amount of the compound of claim 3 and a pharmaceutically acceptable carrier. Since claim 3 claims voriconazole claim 7 reads on a pharmaceutical composition comprising an effective amount of the approved product.

Claim 8 of Patent No. 5,567,817 claims a pharmaceutical composition for treating a fungal infection in a mammal which comprise an effective amount of the compound of claim 4 and a pharmaceutically acceptable carrier. Since claim 4 claims voriconazole claim 8 reads on a pharmaceutical composition comprising an effective amount of the approved product.

Claim 9 of Patent No. 5,567,817 claims a method of treating a fungal infection in a mammal which comprises administering to said mammal an effective amount of the compound of claim 1. Since claim 1 claims voriconazole claim 9 reads on a method of using the approved product for the approved use.

Claim 10 of Patent No. 5,567,817 claims a method of treating a fungal infection in a mammal which comprises administering to said mammal an effective amount of the compound of claim 2. Since claim 2 claims voriconazole claim 10 reads on a method of using the approved product for the approved use.

Claim 11 of Patent No. 5,567,817 claims a method of treating a fungal infection in a mammal which comprises administering to said mammal an effective

amount of the compound of claim 3. Since claim 3 claims voriconazole claim 11 reads on a method of using the approved product for the approved use.

Claim 12 of Patent No. 5,567,817 claims a method of treating a fungal infection in a mammal which comprises administering to said mammal an effective amount of the compound of claim 4. Since claim 4 claims voriconazole claim 12 reads on a method of using the approved product for the approved use.

(10) The relevant dates and information pursuant to 35 U.S.C. §156(g) in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

- An exemption under subsection (i) of section 505 of the Federal Food, Drug and Cosmetic Act became effective for VFEND® (voriconazole) Tablets on September 27, 1995, following receipt by the Food and Drug Administration of Investigational New Drug ("IND") Application No. 48,735 on August 28, 1995.
- A New Drug Application ("NDA") under section 505(b) of the Federal Food, Drug and Cosmetic Act for VFEND® (voriconazole) Tablets was initially submitted on November 17, 2000, as NDA No. 21-266.
- NDA No. 21-266 was approved on May 24, 2002.

(11) A brief description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities is attached hereto as EXHIBIT D.

(12) Applicant is of the opinion that Patent No. 5,567,817 is eligible for an extension under 35 U.S.C. §156. The length of extension claimed is 945 days.

The eligibility requirements of 35 U.S.C. §§156(a) and 156(c)(4) have been satisfied as follows:

- Patent No. 5,567,817 claims a product, VFEND® (voriconazole) Tablets, pharmaceutical compositions including a product, VFEND® (voriconazole) Tablets, and a method of using a product, VFEND® (voriconazole) Tablets.
- Patent No. 5,567,817 is currently set to expire on October 22, 2013 (i.e., the term of the patent has not yet expired).
- The term of Patent No. 5,567,817 has never been extended under subsection (e)(1) of 35 U.S.C. §156.
- This application for extension is being submitted by PFIZER INC., the owner of record of Patent No. 5,567,817, in accordance with the requirements of paragraphs (1) through (4) of 35 U.S.C. §156(d).
- The product, VFEND® (voriconazole) Tablets, has been subject to a regulatory review period under section 505(b) of the Federal Food, Drug and Cosmetic Act before its commercial marketing or use, and the permission for said commercial marketing or use is the first permitted commercial marketing or use of the product under section 505(b) of the Federal Food, Drug and Cosmetic Act.
- No patent has to this date been extended, nor has any other extension been applied for, under subsection (e)(1) of 35 U.S.C. §156, for the regulatory review period which forms the basis for this application for extension of the term of Patent No. 5,567,817.

The length of extension of the term of Patent No. 5,567,817 of 945 days claimed by applicant was determined according to the provisions of 37 C.F.R. §1.775 as follows:

- According to 37 C.F.R. §1.775(b), the length of extension is equal to the regulatory review period for the approved product, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of 37 C.F.R. §1.775.
- According to 37 C.F.R. §1.775(c), the regulatory review period is the sum of: (A) the number of days in the period beginning on the date the

exemption under subsection 505 of the Federal Food, Drug and Cosmetic Act became effective for the approved product and ending on the date the NDA was initially submitted under subsection 505 of the Federal Food, Drug and Cosmetic Act; and (B) the number of days in the period beginning on the date the NDA was initially submitted under subsection 505 of the Federal Food, Drug and Cosmetic Act and ending on the date the NDA was approved. The exemption under subsection 505(i) of the Federal Food, Drug and Cosmetic Act became effective on September 27, 1995; the NDA was initially submitted on November 17, 2000; and the NDA was approved on May 24, 2002. Hence, the regulatory review period under 37 C.F.R. §1.775(c) is the sum of the period from September 27, 1995 to November 17, 2000 and from November 18, 2000 to May 24, 2002. This is the sum of 1,878 days and 552 days, which is 2,430 days.

- According to 37 C.F.R. §1.775(d)(1)(i), the number of days in the regulatory review period which were on and before the date on which the patent issued must be subtracted. Patent No. 5,567,817 issued on October 22, 1996. Subtraction of the period on and before October 22, 1996 leaves a reduced regulatory review period from October 23, 1996 to November 17, 2000 and from November 18, 2000 to May 24, 2002. This is the sum of 1,486 days and 552 days, which is 2,038 days.
- 37 C.F.R. §1.775(d)(1)(ii) does not apply.
- According to 37 C.F.R. §1.775(d)(1)(iii), the regulatory review period must then be reduced by one-half of the days remaining in the period defined in 37 C.F.R. §1.775(c)(1). This is one-half of 1,486 days, which is 743 days. After subtraction, this now leaves a reduced regulatory review period of 743 days plus 552 days, which is 1,295 days.
- According to 37 C.F.R. §1.775(d)(2), the reduced regulatory review period of 1,295 days must be added to the expiration date of Patent No. 5,567,817 (i.e., October 22, 2013). This gives a date of May 9, 2017. According to 37 C.F.R. §1.775(d)(3), 14 years must be added to the date of approval of the approved product. This gives a date of May 24, 2016. According to 37 C.F.R. §1.775(d)(4), the earlier of these dates must be

selected. The earlier of these dates is May 24, 2016 (i.e., 945 days beyond the expiration date of the 5,567,817 patent).

- The provisions of 37 C.F.R. §1.775(d)(5) apply to this application, because Patent No. 5,567,817 issued after September 24, 1984. Pursuant to 37 C.F.R. §1.775(d)(5)(i) five (5) years are added to the expiration date of Patent No. 5,567,817 (October 22, 2013) giving a date of October 22, 2018. According to 37 C.F.R. §1.775(d)(5)(ii), the dates obtained pursuant to 37 C.F.R. §1.775(d)(5)(i) and 37 C.F.R. §1.775(d)(4) are compared and the earlier date is selected. The date calculated according to 37 C.F.R. §1.775(d)(4) above is May 24, 2016. Therefore, the earlier of these dates is May 24, 2016. Applicant is entitled to an extension of term of Patent No. 5,567,817 until May 24, 2016, i.e., an extension of 945 days from original expiration date of October 22, 2013.
- 37 C.F.R. §1.775(d)(6) does not apply because Patent No. 5,567,817 issued on October 22, 1996, after September 24, 1984.

(13) Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension of 945 days which is being sought to the term of Patent No. 5,567,817.

(14) The prescribed fee under 37 C.F.R. §1.20(j) for receiving and acting on this application for patent term extension is to be charged to Deposit Account No. 16-1445, as requested in the enclosed transmittal letter.

(15) Please direct all inquiries and correspondence relating to this application for patent term extension as follows:

Adrian G. Looney
PFIZER INC.
Legal Division
150 East 42nd Street
New York, NY 10017-5755

Tel: (212) 733-1038
Fax: (212) 573-1939

Pursuant to 37 C.F.R. §1.740(b), two duplicate copies of these application papers are enclosed herewith. Pursuant to M.P.E.P. §2753 an additional two copies of the application are also enclosed herewith. Accordingly, a total of four

copies of the application and one original application for patent term extension of Patent No. 5,567,817 are submitted herewith.

Applicant respectfully requests prompt and favorable action on the merits of this application for extension of the term of Letters Patent No. 5,567,817 of 945 days, based on the regulatory review period for VFEND® (voriconazole) Tablets.

Respectfully submitted,
PFIZER INC.

Date: July 15, 2002

Adrian G. Looney
Attorney for Applicant
Reg. No. 41,406
Tel.: (212) 573-4585

PFIZER INC.
Legal Division
150 East 42nd Street
New York, NY 10017-5755

US5567817A

Exhibit A

United States Patent [19]

Ray et al.

[11] Patent Number: 5,567,817

[45] Date of Patent: Oct. 22, 1996

[54] TRIAZOLE ANTIFUNGAL AGENTS

[75] Inventors: **Stephen J. Ray**, Deal; **Kenneth Richardson**, Birchington; both of England

[73] Assignee: **Pfizer Inc.**, New York, N.Y.

[21] Appl. No.: **432,414**

[22] Filed: **May 1, 1995**

Related U.S. Application Data

[60] Continuation of Ser. No. 139,972, Oct. 20, 1993, abandoned, which is a division of Ser. No. 956,569, Oct. 5, 1992, Pat. No. 5,278,175, which is a continuation of Ser. No. 646,564, Jan. 25, 1991, abandoned.

[30] **Foreign Application Priority Data**

Feb. 2, 1990 [GB] United Kingdom 9002375

[51] **Int. Cl.**[6] **C07D 403/10**

[52] **U.S. Cl.** **544/333**

[58] **Field of Search** 544/333; 514/256

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,952,232	8/1990	Cuomo et al.	71/92
5,116,844	5/1992	Dickinson et al.	514/269

FOREIGN PATENT DOCUMENTS

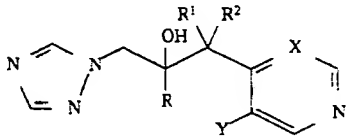
332387	9/1989	European Pat. Off. .	
3813841	12/1988	Germany	548/266.6

Primary Examiner—Patricia L. Morris

Attorney, Agent, or Firm—Peter C. Richardson; Paul H. Ginsburg; Bryan C. Zielinski

[57] **ABSTRACT**

The invention provides antifungal compounds of the formula:



(I)

and pharmaceutical salts thereof,
wherein

R is phenyl substituted by 1 to 3 substituents each independently selected from halo, —CF_3 and —OCF_3;

R^1 is C_1–C_4 alkyl;

R^2 is H or C_1–C_4 alkyl;

X is CH or N; and

Y is F or Cl.

12 Claims, No Drawings

B

Date Mailed: June 14, 2002 Express Mail No. EL 162816088US

Serial No. 08/432,414 Docket No. PC7704C By BCZ

Application of STEPHEN J. RAY, ET AL. Filing Date MAY 1, 1995

Entitled TRIAZOLE ANTIFUNGAL AGENTS

The following, has been received in the United States Patent and Trademark Office on the date stamped hereon:

- ☐ Application Transmittal *Type*
- ☐ Specification *pages*
- ☐ Claims *pages*
- ☐ Abstract *pages*
- ☐ Drawing(s) *sheets*
- ☐ Declaration with Power of Attorney
- ☐ Priority Document
- ☐ Information Disclosure Statement
- ☐ Form PTO-FB-A820 (Citation List) References
- ☐ Sequence Submission (☐ Computer Readable Copy, ☐ Paper copy ☐ Identity Statement)
- ☐ Copy of Notice to File Missing Parts, Cover Letter
- ☐ Amendment - Preliminary
- ☐ Reply
- ☐ Notice of Appeal
- ☐ Brief (3 copies)
- ☐ Issue Fee Transmittal 2 pages
- ☐ Fee Address Indication Form
- ☐ Certificate of Correction
- ☐ Petition for Extension of Time 2 copies
- ☐ Fee Transmittal (2 copies)
- ☐ Associate Power of Attorney
- ☐ Petition for Expedited Issuance for Foreign Filing License
- ☐ Assignment & Recordation Cover Sheet
- ☒ Request for Certificate of Correction
- ☒ Form 1050
- ☒ Assignment (copy)

MAILING REQUEST

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ORIGINATED BY: Natalie Ullmann

DATE: June 14, 2002

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QUANTITY	COMPLETE DESCRIPTION
1	Legal Doc. Re: PC7704C.AGL

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Patent Application
Attorney Docket No. PC7704C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: :

STEPHEN J. RAY, ET AL.

Examiner: Morris, P.

PATENT NO.: 5,567,817 :

Group Art Unit: 1201

ISSUE DATE: OCTOBER 22, 1996 :

TITLE: TRIAZOLE ANTIFUNGAL AGENTS :

Commissioner for Patents
Washington, D.C. 20231

Sir:

REQUEST FOR CERTIFICATE OF CORRECTION

PFIZER INC., assignee of 100% interest on the above-identified patent, requests issuance of a Certificate of Correction, pursuant to 37 C.F.R. §1.322, in connection with the above-identified patent deed. A copy of the relevant assignment document is also attached hereto confirms that Pfizer Inc. is the assignee of 100% interest in the patent.

The error to be corrected is listed in a Form PTO-1050, which is attached hereto in duplicate.

The error is that claim 6, column 31, lines 3-6, is missing the dependent claim reference numeral –2--. Support for the correction can be found in the original specification of the above patent and in Amendment of claims submitted for the subject application on May 16, 1996.

Because the error described above was the fault of the United States Patent and Trademark Office and, thus, correction thereof is under 37 C.F.R. §1.322, it is believed that no fee is due for issuance of the Certificate of Correction. However, if any fee is required under 37 C.F.R. §1.20, authorization is provided to charge the appropriate fee to Pfizer Deposit Account No. 16-1445. Two copies of this letter are enclosed.

Respectfully submitted,

Dated: 6/13/02

Pfizer Inc.
Patent Department, 5th Floor
150 East 42nd Street
New York, NY 10017
(212) 573-4585

Bryan C. Zielinski
ATTORNEY for Applicants
Reg. No. **34,462**

EXPRESS MAIL NO.: **EL 162816088US**

Patent Application
Attorney Docket No. PC7704C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Respectfully submitted,

Dated: 6/15/02

Pfizer Inc.
Patent Department, 5th Floor
150 East 42nd Street
New York, NY 10017
(212) 573-4585

Bryan C. Zielinski
ATTORNEY for Applicants
Reg. No. **34,462**

EXPRESS MAIL NO.: **EL 162816088US**

PTO/SB/ 44 (10-96)
Approved for use through 6/30/99. OMB 0651-0033
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO : 5,567,817

DATED : October 22, 1996

INVENTOR(S) : STEPHEN J. RAY and KENNETH RICHARDSON

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 31, line 5, insert the claim reference numeral -- 2 -- between the words "claim" and "and" in dependent claim 6.

MAILING ADDRESS OF SENDER:
Pfizer Inc.
Patent Department - Legal Division
235 East 42nd Street
New York, NY 10017

PATENT NO. 5,278,175
No. of additional copies

Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

TO: JAMES M. MCMANUS
PFIZER INC.
PATENT DEPARTMENT
EASTERN POINT ROAD
GROTON, CT 06340

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

COPY TO NEW YORK 4/5/91 AV

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE U.S. PATENT AND TRADEMARK OFFICE ON THE REEL AND FRAME NUMBER REFERENCED BELOW. A DIGEST OF THE DOCUMENT HAS ALSO BEEN MADE AND APPEARS IN THE OFFICE'S RECORDS AS SHOWN:

ASSIGNOR: 001 PFIZER LIMITED DOC DATE: 01/18/91

RECORDATION DATE: 01/25/91 NUMBER OF PAGES 004 REEL/FRAME 5580/0166

DIGEST: ASSIGNMENT OF ASSIGNORS INTEREST

ASSIGNEE: 501 PFIZER INC., 235 EAST 42ND STREET, NEW YORK, NY, A CORP. OF DE

SERIAL NUMBER	7-646564	FILING DATE	01/25/91
PATENT NUMBER		ISSUE DATE	00/00/00

PATENT
PC7704JMM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: : ASSIGNMENT BRANCH
STEPHEN J. RAY ET AL. :

FOR: TRIAZOLE ANTIFUNGAL AGENTS :

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

RECORDAL OF ASSIGNMENT

Enclosed herewith is the executed Assignment for the above-referenced application for recordal by the Assignment Branch of the U.S. Patent and Trademark Office.

Please charge Deposit Account No. 16-1445 the amount of $8.00 and any additional fees required. Two copies of this letter are enclosed.

Respectfully submitted,

Date: January 24, 1991

James M. McManus
Agent for Applicants
Reg. No. 28,642
Tel.: (203) 441-4903

Pfizer Inc.
Patent Department
Eastern Point Road
Groton, CT 06340

EXPRESS MAIL CERT. NO. FB139135469US

LA1239 02/01/91 07490564 16-1445 01C 1/90 M.3 (1/1)

CONSENT OF PFIZER LIMITED

Whereas by virtue of the terms of employment with PFIZER LIMITED of Ramsgate Road, Sandwich, Kent, England, PFIZER LIMITED is entitled to an assignment of the entire right, title and interest in and to all inventions, whether joint or sole, made by STEPHEN J. RAY and KENNETH RICHARDSON and whereas PFIZER LIMITED desires that PFIZER INC. receive the full benefits of the foregoing assignment by its aforesaid employee(s), PFIZER LIMITED by the duly authorized signature of the undersigned officer, hereby consents to the foregoing assignment by its aforesaid employee(s).

Signed this 18th day of January, 1991

PFIZER LIMITED

By: ______________________
(Name) Anthony Alister Dunning
(Title) Director for Pfizer Limited

In the presence of:

____
Witness

Mary Derrane
(Typed and Printed Name of Witness)

PFIZER INC.,
EASTERN POINT ROAD
GROTON, CONNECTICUT 06340

PC7704JMM
Joint Inventors
Pfizer - US

A S S I G N M E N T

For valuable consideration, the receipt and adequacy of which is hereby acknowledged, we, STEPHEN J. RAY and KENNETH RICHARDSON of "Tremissary", Edward Road, Kingsdown, Deal, Kent, (Street) (City) (County) (State/Country) England; and 12, Grenham Road, Birchington, Kent, England;

respectively, hereby sell, assign, and transfer unto PFIZER INC., a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, New York, the entire right, title, and interest in and to our application for Letters Patent of the United States, executed the 18th day of January, 1991, entitled

TRIAZOLE ANTIFUNGAL AGENTS

and our entire right, title, and interest in the United States in and to all our inventions, whether joint or sole, disclosed in said application for Letters Patent, and in and to all United States patents granted on the foregoing inventions, and we hereby agree, whenever

requested, to communicate to said assignee, its successors and assigns, any facts known to us respecting said inventions, to testify in any legal proceeding, and to execute all applications or papers necessary to obtain and maintain proper patent protection on said inventions in the United States.

Signed and sealed this 18th day of January 1991 at Sandwich, Kent, England
(City, State)

Stephen J. Ray (SEAL)
(Applicant No. 1)
STEPHEN J. RAY

In the presence of:

(Witness as to Applicant No. 1)

H.M. WHIPP
(Typed or Printed Name of Witness)

Signed and sealed this 18th day of January 1991 at Sandwich, Kent, England
(City, State)

Kenneth R. Richardson (SEAL)
(Applicant No. 2)
KENNETH RICHARDSON

In the presence of:

(Witness as to Applicant No. 2)

H.M. WHIPP
(Typed or Printed Name of Witness)

Pfizer Inc.
Patent Dept.
Eastern Point Road
Groton, CT 06340

Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 2

C

000127

M75N9

PFIZER INC.
PATENT DEPARTMENT
235 EAST 42ND STREET, FLOOR 20
NEW YORK NY 10017-5755

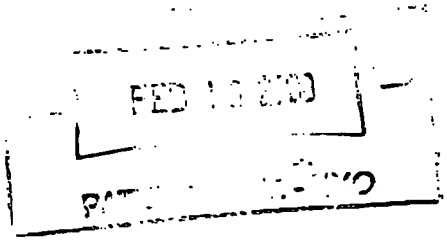
MAINTENANCE FEE STATEMENT

The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 11, "STAT" below.

If a maintenance fee payment is defective, the reason is indicated by code in column 11, "STAT" below. TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(k) and (l).

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.

ITEM NBR	PATENT NUMBER	FEE CDE	FEE AMT	SUR CHARGE	SERIAL NUMBER	PATENT DATE	FILE DATE	PAY YR	SML ENT	STAT
1	5,567,817	183	830	----	08/432,414	10/22/96	05/01/95	04	NO	PAID



ITM NBR	ATTY DKT NUMBER

**DIRECT THE RESPONSE TOGETHER WITH ANY QUESTIONS ABOUT THIS NOTICE TO:
COMMISIONER OF PATENTS AND TRADEMARKS, BOX M. FEE, WASHINGTON, D.C. 20231**

PTOL-439 (REV. 11-97)

BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	28-AUG-95	INITIAL IND SUBMISSION: VORICONAZOLE TABLETS
R	01-SEP-95	FDA LETTER: ASSIGNING IND 48,735
R	11-OCT-95	FDA FAX: COMMENTS FROM OPHTHALMOLOGIC CONSULT
S	12-OCT-95	RESPONSE: SAMPLE INFORMED CONSENT AND RATIONALE FOR DOSE ESCALATION STUDY
S	09-NOV-95	REQUEST FOR COMMENTS/MEETING TO DISCUSS CLINICAL DEVELOPMENT PROGRAM
S	05-DEC-95	PROTOCOL AMENDMENT: 95CK39-0673
R	13-DEC-95	FDA FAX: CHEMISTRY REQUIREMENTS FOR PHASE 3 STUDIES
S	21-DEC-95	NEW INVESTIGATORS FOR PR 95CK39-0673
S	16-JAN-96	CMC AMENDMENT
R	26-JAN-96	FDA LETTER: CHEMISTRY REQUIREMENTS FOR PHASE 3 STUDIES
S	02-FEB-96	SAFETY REPORTS: PSORIASIS VULGARIS AND EOSINOPHILIA; ATRIAL FIBRILLATION
M	14-FEB-96	TELECON: DEVELOPMENT PLAN
S	18-MAR-96	MINUTES OF 14-FEB-96 TELECONFERENCE
S	22-MAR-96	CMC AMENDMENT
S	12-APR-96	PROTOCOL AMENDMENT 95CK39-0673
S	01-MAY-96	REQUEST FOR END OF PHASE 2 MEETING

S = Submission to FDA
R = Received from FDA
M= Meeting with FDA (in person or teleconference)

BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	13-MAY-96	CMC: LOT DATA FOR CLINICAL SUPPLIES
S	14-MAY-96	NEW INVESTIGATORS FOR PR 95CK39-0673
S	17-MAY-96	END OF PHASE 2 PRE-MEETING PACKAGE
S	17-MAY-96	DETAILS FOR 24-JUNE-96 END OF PHASE 2 MEETING
S	23-MAY-96	DOSE LEVEL RATIONALE FOR CARCINOGENICITY STUDIES
R	29-MAY-96	FDA FAX: FDA COMMENTS ON ORIGINAL IND APPLICATION 4/23/96
S	30-MAY-96	NEW INVESTIGATORS FOR PR 95CK39-0673
S	11-JUN-96	CMC: 5-FLUROURACIL AS RAW MATERIAL
S	19-JUN-96	TRANSPARENCIES FOR END OF PHASE 2 MEETING ON 24-JUN-96
M	24-JUN-96	END OF PHASE 2 MEETING
S	28-JUN-96	NEW INVESTIGATORS FOR PR 95CK39-0673
S	09-JUL-96	NEW INVESTIGATORS FOR PR 95CK39-0673
R	19-JUL-96	FDA FAX: COMMENTS REGARDING THE PROPOSED POPULATION PK SAMPLING SCHEME FOR PROTOCOL 150-602
R	25-JUL-96	FDA LETTER: END OF PHASE 2 MEETING MINUTES AND PARTICIPANTS
S	29-JUL-96	PFIZER MINUTES OF END OF PHASE 2 MEETING HELD ON 24-JUN-96
R	02-AUG-96	FDA FAX: BIOPHARM COMMENTS

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	02-AUG-96	PROTOCOL AMENDMENT: 95-N-0141 MOD
S	05-AUG-96	NEW INVESTIGATORS FOR PR 95CK39-0673
S	08-AUG-96	RESPONSES TO QUESTIONS ON CARCINOGENICITY STUDIES
S	08-AUG-96	RESPONSE TO DR OWEN MCMASTER (PHARM/TOX REVIEWER)
R	14-AUG-96	FDA LETTER: END OF PHASE 2 COMMENTS AND RECOMMENDATIONS
S	12-SEP-96	ADDITIONAL INFORMATION ON RAW MATERIALS
S	16-SEP-96	MINUTES OF 15-AUG-96 TELECON RE: PROPOSED CARCINOGENICITY STUDIES
S	16-SEP-96	MONTHLY REPORT
S	16-SEP-96	NEW INVESTIGATORS FOR PR 95CK39-0673
S	23-SEP-96	REQUEST FOR TWO MEETINGS: CMC & ANIMAL STUDIES
S	11-OCT-96	RESPONSE: CMC & PHARM/TOX COMMENTS FROM 29-MAY-96 FDA FAX
S	14-OCT-96	ANNUAL REPORT (JUN-96)
S	25-OCT-96	SAFETY REPORT: RENAL FAILURE AND DECREASED PROTHROMBIN ACTIVITY
S	25-OCT-96	SAFETY REPORT: THROMBOSIS
S	21-NOV-96	PROTOCOL AMENDMENT 96CK39-0673
S	04-DEC-96	RESPONSE TO 2-AUG-96 FDA FAX

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
R	09-JAN-97	FDA LETTER: ALLOW CUSTOMS RELEASE OF 5-FLUOROURACIL
S	03-FEB-97	PROTOCOL AMENDMENT 150-602; RESPONSES TO IND REVIEW QUESTIONS
S	14-FEB-97	17-JAN-97 MEETING MINUTES
S	07-APR-97	INVESTIGATOR'S BROCHURE (NOV-96)
S	15-MAY-97	SAFETY REPORT: HEPATITIS
S	02-JUN-97	PROTOCOL AMENDMENT 150-602
S	01-JUL-97	NEW PROTOCOLS 150-604, 150-607
S	18-JUL-97	PROPOSAL FOR SINGLE COMBINED ANALYSIS OF PROTOCOLS 150-602 AND 307 (UMBRELLA PROTOCOL)
S	23-JUL-97	MONTHLY REPORT
S	25-JUL-97	NEW PROTOCOL 150-606
S	21-AUG-97	MEETING MINUTES (17-JAN-97 & 19-JAN-95) WITH VARIOUS DIVISIONS AND DAVDP; OVERVIEW OF SBECD COMPONENT FOR TOX PACKAGE
S	21-AUG-97	RESPONSE TO REQUEST FOR INFORMATION RE PROT 602
S	22-AUG-97	MONTHLY REPORT
S	28-AUG-97	LETTER OF CROSS REFERENCE – SINGLE EMERGENCY USE
S	19-SEP-97	MONTHLY REPORT
S	22-SEP-97	PRECLINICAL STUDY REPORTS

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	25-SEP-97	PROTOCOL 604 AMENDMENT
S	06-OCT-97	MONTHLY REPORT
S	16-OCT-97	TELECON ON POSSIBLE CHANGES TO CLINICAL PROGRAM (ASPERGILLOSIS AND ESOPHAGEAL CANDIDIASIS)
S	20-OCT-97	INFORMATIONAL AMENDMENT: RENAL IMPAIRMENT
S	20-OCT-97	SAFETY REPORT: ACUTE PANCREATITIS
S	30-OCT-97	MONTHLY REPORT
S	03-NOV-97	RESPONSE TO FDA REQUEST: PK SYNOPSES FOR PROTOCOLS 150-228, 229, 233; PRELIMINARY DATA FOR WARFARIN AND DIGOXIN INTERACTION STUDIES
S	06-NOV-97	ANNUAL REPORT (PERIOD ENDING JUN-97)
S	11-NOV-97	NEW PROTOCOL: 150- 603
S	24-NOV-97	MONTHLY REPORT
S	19-DEC-97	MONTHLY REPORT
M	17, 18, 19, 22-DEC-97	TELECONS: FDA COMMENTS ON EMPIRICAL PROTOCOL 150-603
R	22-DEC-97	FDA FAX: TELECONFERENCE SCHEDULED FOR DEC-23
S	30-DEC-97	FAX TO CLARIFY POINTS DISCUSSED DURING 12/23 TELECON
S	09-JAN-98	MONTHLY REPORT
S	12-JAN-98	PROT 603 FEVER INCLUSION CRITERIA; CRITERION FOR UTI

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	04-FEB-98	NEW PROTOCOL 150-608
S	06-FEB-98	MONTHLY REPORT
S	11-FEB-98	PREMEETING PACKAGE FOR 25-FEB-98 MEETING
S	17-FEB-98	FINAL PLAN FOR COMBINED STATISTICAL ANALYSIS OF STUDIES 602 AND 307 (UMBRELLA ANALYSIS)
S	24-FEB-98	OVERHEADS TO BE USED AT END OF PHASE 2 MEETING
S	25-FEB-98	END OF PHASE 2 MEETING
S	26-FEB-98	MONTHLY REPORT
R	10-MAR-98	FDA FAX: TELECONFERENCE SCHEDULED MAR 13 ON COMMENTS ON 150-608
S	13-MAR-98	INVESTIGATOR'S BROCHURE (DEC-97)
S	17-MAR-98	MONTHLY REPORT
M	23-MAR-98	TELECON RE: RESPONSE TO FDA QUERY RE TYPE 1 ERROR IN PROTOCOL 150-608
S	01-APR-98	END OF PHASE 2 MEETING MINUTES
S	01-APR-98	SAFETY REPORT: SEVERE HYPOTENSION AND PROBABLE DRUG INTERACTION (VORICONAZOLE/LORAZEPAM)
S	15-APR-98	NEW PROTOCOL: 001-5001
S	15-APR-98	PROTOCOL 602 AMENDMENT
S	17-APR-98	MONTHLY REPORT
S	28-APR-98	PROTOCOLS 603/604/606/607/608 SAFETY REPORTING AMENDMENTS

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	04-MAY-98	SAFETY REPORT: THROMBOCYTOPENIA AND BONE MARROW APLASIA (TELEPHONE RPT 5/1)
S	08-MAY-98	POSITION PAPER ON VORICONAZOLE AND ALTERED VISION
S	12-MAY-98	MONTHLY REPORT
S	12-MAY-98	PROTOCOL 150-608 AMENDMENT
S	15-MAY-98	PROTOCOL 673 AMENDMENT
S	28-MAY-98	RESPONSES TO BIOPHARMACEUTICS COMMENTS ON 150-608 (3/10 FDA FAX)
S	29-MAY-98	MONTHLY REPORT
S	16-JUN-98	MONTHLY REPORT
S	23-JUN-98	SAFETY REPORT: FOLLOW UP TO MAY 4 SAFETY LETTER
S	06-JUL-98	MONTHLY REPORT
M	10-JULY-98	STATUS OF REVIEW OF SBECD PROPOSAL AND VISUAL POSITION PAPER
S	21-JUL-98	MONTHLY REPORT
S	28-JUL-98	INFORMATION AMENDMENT: MISSING PAGES FROM VISUAL AE PAPER
S	07,21-AUG-98	MONTHLY REPORT
S	03,14-SEP-98	MONTHLY REPORT
R	09-OCT-98	FDA FAX: COMMENTS ON POSITION PAPER ON VORICONAZOLE AND ALTERED VISION

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	09-OCT-98	ANNUAL REPORT
S	01,13-OCT-98	MONTHLY REPORT
S	30-OCT-98	MONTHLY REPORT
S	30-OCT-98	PFIZER REQUEST FOR FDA MINUTES OF 2/25/98 EOP2 MEETING; REQUEST FOR TELECON ON VISUAL EFFECTS AND EOP2 CMC MEETING
S	04-NOV-98	REQUEST FOR CLARIFICATION OF VISUAL ADVERSE EVENT COMMENTS
M	16-NOV-98	TELECON TO CLARIFY FDA COMMENTS ON VISUAL AE POSITION PAPER
S	17,30-NOV-98	MONTHLY REPORT
S	09-DEC-98	PROTOCOL 150-001 AMENDMENT
S	09,23-DEC-98	MONTHLY REPORT
S	06-JAN-99	INFORMATIONAL AMENDMENT: VISUAL DISTURBANCES AND CHANGE IN MENTAL STATUS
S	07-JAN-99	REQUEST FOR END OF PHASE 2 CMC MEETING
S	08,12-JAN-99	MONTHLY REPORTS
S	28-JAN-99	INVESTIGATOR'S BROCHURE (DEC-98)
M	03-FEB-99	END OF PHASE 2 CMC MEETING
S	09-FEB-99	INFORMATIONAL AMENDMENT: FOLLOW UP TO SAFETY LETTER DATED JANUARY 6, 1999
M	11-FEB-99	SECOND END OF PHASE 2 MEETING
S	09,17-FEB-99	MONTHLY REPORT

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	25-FEB-99	PRE-MEETING INFORMATION (3/10 MEETING)
S	03-MAR-99	MONTHLY REPORT
M	10-MAR-99	MEETING RE: FINAL DATA FROM ASPERGILLOSIS STUDY 150-304 AND OTHER ISSUES
R	11-MAR-99	FDA FAX: FEB-3 MEETING MINUTES ON CMC PROGRAM
R	22-MAR-99	FDA FAX: MEMO OF NOV-16 TELECONFERENCE TO DISCUSS OPHTHALMOLOGIC ADVERSE EVENTS
S	22-MAR-99	SAFETY REPORT: VENTRICULAR FIBRILLATION AND CARDIAC ARREST (CANADA) (TELEPHONE REPORT MADE 3/15)
S	23-MAR-99	MONTHLY REPORT
M	06-APR-99	TELECON TO DISCUSS CANADIAN DEATH (ARRHYTHMIA)
R	08-APR-99	FDA FAX: 4/6 TELECONFERENCE RE 3/15 REPORT OF CARDIAC ARRHYTHMIA
S	08-APR-99	MONTHLY REPORT
S	12-APR-99	PROTOCOL 150-608 AMENDMENT
S	20-APR-99	CASES OF LIFE-THREATENING CARDIAC EVENTS
M	21-APR-99	PROPOSED PROTOCOL AMENDMENTS RE CARDIAC SAFETY
S	28-APR-99	MONTHLY REPORT
S	06-MAY-99	DRAFT PROTOCOL A1501003
S	14-MAY-99	TELECON RE: DRAFT PROTOCOL FOR HISTORICAL CONTROL STUDY IN ASPERGILLOSIS PATIENTS
S	12,20-MAY-99	MONTHLY REPORT

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	24-MAY-99	SAFETY REPORT: DEPAKOTE TOXICITY AND PANCYTOPENIA
S	27-MAY-99	MONTHLY REPORT
S	14-JUN-99	SAFETY REPORT: FOLLOW UP TO SAFETY LETTER DATED MARCH 22, 1999
S	15-JUN-99	MONTHLY REPORT
S	23-JUN-99	PRE-MEETING INFORMATION (7/7/ MEETING) ON OPHTHAL TESTING AND PRESENTATION OF LIVER FUNCTION DATA IN NDA
S	24-JUN-99	REQUEST FOR TRADENAME APPROVAL
S	24-JUN-99	RESPONSE TO FDA REQUEST FOR INFORMATION ON STEREOISOMERS
S	25-JUN-99	SAFETY REPORT: POSSIBLE TACROLIMUS/VORICONAZOLE DRUG INTERACTION
S	01-JUL-99	MONTHLY REPORT
M	07-JUL-99	MEETING RE: VISUAL ADVERSE EVENTS AND LIVER FUNCTION DATA PRESENTATION IN NDA
S	16,29-JUL-99	MONTHLY REPORT
S	29-JUL-99	PROTOCOLS 150-602, 604 AMENDMENTS
S	06-AUG-99	PROTOCOL AMENDMENTS ON CARDIAC SAFETY (STUDIES 602, 604, 606, 607, 608)
S	06,12-AUG-99	MONTHLY REPORT
R	13-AUG-99	FDA FAX: MINUTES OF 7/7/99 MEETING
S	18-AUG-99	SAFETY REPORT: POSSIBLE INTERACTION BETWEEN CLARITHROMYCIN AND VORICONAZOLE

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	23-AUG-99	PRE-NDA LETTER: PROPOSED DATA PRESENTATIONS (DATASETS, ISS, ISE)
S	01-SEP-99	MONTHLY REPORT
S	03-SEP-99	NEW PROTOCOL A1501003 AND 150-304
S	13-SEP-99	STATUS TABLES OF PHARM STUDIES; 12 CLIN PHARM STUDY REPORTS
S	15-SEP-99	MONTHLY REPORT
R	17-SEP-99	TELECON RE: ELECTRONIC REGULATORY SUBMISSION (ESUB) ISSUES
R	20-SEP-99	FDA FAX: COMMENT ON PROTOCOL AMENDMENT AND CONTACT INFORMATION FOR BETA-TESTING OF PHARMACOKINETIC SOFTWARE
S	21-SEP-99	MONTHLY REPORT
R	22-SEP-99	FDA FAX: COMMENTS ON PROTOCOL AMENDMENT
S	29-SEP-99	CMC AMENDMENT
S	06-OCT-99	INVESTIGATOR'S BROCHURE (SEP-99)
S	08-OCT-99	FINAL STUDY REPORT 150-230
S	14-OCT-99	PROTOCOL 150-607 AMENDMENT
S	14,22-OCT-99	MONTHLY REPORTS
R	03-NOV-99	FDA FAX: COMMENTS ON PROTOCOLS 150-304 & A1501003
S	03-NOV-99	PROTOCOL A1501004 - REQUEST FOR COMMENTS

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	DATE	COMMENTS
S	04-NOV-99	MONTHLY REPORT
M	08-NOV-99	TELECON: FDA REQUEST FOR DATA FROM ASPERGILLOSIS HISTORICAL CONTROL PROTOCOL
S	12-NOV-99	ANNUAL REPORT (PERIOD ENDING JUN-99)
S	16-NOV-99	PRE-MEETING BRIEFING DOCUMENT FOR 12/3 MEETING ON PEDIATRIC PROGRAM
R	18-NOV-99	FDA FAX: COMMENTS ON PROTOCOL A1501004
S	22-NOV-99	MONTHLY REPORT
M	23,24-NOV-99	TELECONS RE: TWO CARDIAC EVENTS
S	24-NOV-99	RESPONSE TO FAX RECEIVED 9/20/99
R	30-NOV-99	FDA COMMENTS ON ERG PROTOCOL
M	03-DEC-99	MEETING ON CLINICAL PHARMACOLOGY AND PEDIATRIC PROGRAMS
S	07-DEC-99	MONTHLY REPORT
S	08-DEC-99	INFORMATIONAL AMENDMENT: VENTRICULAR TACHYCARDIA
S	07-JAN-00	MONTHLY REPORT
S	12-JAN-00	GENERAL CORRESPONDENCE: RE SIRIUS, FDA GUIDANCES ON ELECTRONIC SUBMISSIONS
S	12-JAN-00	INFORMATION AMENDMENT: TOXICOLOGY 96018 (MOUSE CARCINOGENICITY STUDY)
S	18-JAN-00	RESPONSE TO FDA REQUEST FOR INFORMATION
S	19-JAN-00	MONTHLY REPORT

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	DATE	COMMENTS
S	01-FEB-00	A1501004 AMENDMENT (26-NOV-1999)
S	02-FEB-00	MONTHLY REPORT
R	04-FEB-00	FDA FAX: RECORD OF DECEMBER 4 1999 MEETING ON THE SUBJECT OF PEDIATRIC PROGRAM AND CLINICAL PHARMACOLOGY OF VORICONAZOLE
S	04-FEB-00	GENERAL CORRESPONDENCE: PEDS SINGLE DOSE AND MULTIDOSE STUDY
S	08-FEB-00	REQUEST FOR TELECONFERENCE: SINGLE DOSE PEDIATRIC PHARMACOKINETICS
S	11-FEB-00	UPCOMING TELECONFERENCE ON PEDIATRIC PHARMACOKINETIC STUDIES (PROTOCOL 150-249)
S	16-FEB-00	MONTHLY REPORT
R	18-FEB-00	FDA LETTER: TYPE C TELECONFERENCE FOR MARCH 1 2000 TO DISCUSS DATA FOR PEDIATRIC PK STUDY
S	18-FEB-00	SAFETY REPORT: POSSIBLE INTERACTION BETWEEN DALFOPRISTIN/QUINUPRISTIN AND VORICONAZOLE
S	23-FEB-00	RESPONSE TO COMMENTS FROM FDA CLINICAL PHARMACOLOGIST AND MICROBIOLOGIST (FDA FAX 9/22/00)
S	25-FEB-00	GENERAL CORRESPONDENCE FOR DRAFT PROTOCOL A1501007
M	01-MAR-00	TELECON RE: SINGLE DOSE PEDIATRIC PK STUDY AND ASPECTS OF MULTIDOSE STUDY
R	02-MAR-00	CLINICAL PHARMACOLOGY COMMENTS AS DISCUSSED DURING 3/1 TELECON
S	02-MAR-00	INFORMATIONAL AMENDMENT: VENTRICULAR TACHYCARDIA
S	02-MAR-00	PROTOCOL A1501010 AMENDMENT
S	08-MAR-00	MONTHLY REPORT

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
R	10-MAR-00	FDA MINUTES OF 7/7/99 AND 9/17/99 MEETINGS
S	15-MAR-00	SAFETY REPORT: DEATH DUE TO LIVER FAILURE (TELEPHONE REPORT MADE 3/14)
S	16-MAR-00	NEW PROTOCOL A1501007
S	23-MAR-00	MONTHLY REPORT
S	27-MAR-00	REQUEST FOR CMC PRE-NDA MEETING
S	29-MAR-00	REQUEST FOR TELECONFERENCE ON ELECTRONIC SUBMISSION ISSUES
S	06-APR-00	MONTHLY REPORT
S	10-APR-00	PRE-MEETING INFORMATION FOR 5/16 CMC MEETING
R	13-APR-00	COMMENTS ON PROTOCOL A1501007
S	24-APR-00	PROTOCOL AMENDMENT: 150-606
S	26-APR-00	MONTHLY REPORT
S	01-MAY-00	PRE-MEETING BACKGROUND PACKAGE: TECHNICAL ASPECTS OF THE NDA
S	05-MAY-00	GENERAL CORRESPONDENCE: PRE-MEETING INFORMATION RE: 16-MAY-00 PRE-NDA CMC VIDEOCONFERENCE
S	05-MAY-00	TOXICOLOGY REPORT #96107: 12-MONTH DOG STUDY
S	05-MAY-00	SAFETY REPORT: COMPLETE ATRIOVENTRICULAR BLOCK (TELEPHONE REPORT ON 4/28)
S	11-MAY-00	GENERAL CORRESPONDENCE: REQUEST FOR PRE-NDA MEETING

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	DATE	COMMENTS
S	11-MAY-00	SAFETY REPORT: POSSIBLE MULTIPLE DRUG INTERACTION AMONG VORICONAZOLE, CYCLOSPORINE, AND ACYCLOVIR
S	11-MAY-00	TOXICOLOGY REPORT: 24-MONTH RAT CARCINOGENICITY STUDY
S	16-MAY-00	PFIZER AND FDA MEETING MINUTES OF 2/3/99 CMC MEETING
S	16-MAY-00	ALL AVAILABLE DATA ON CARDIAC EFFECTS
M	16-MAY 00	VIDEOCONFERENCE: PRE-NDA CMC MEETING
M	31-MAY-00	TELECON: TECHNICAL ASPECTS OF NDAs
S	01-JUN-00	MONTHLY REPORT
R	07-JUN-00	FDA FAX: REQUEST FOR INFORMATION
S	09-JUN-00	MONTHLY REPORT
S	14-JUN-00	NEW PROTOCOL A1501011
S	16-JUN-00	PFIZER MINUTES OF PRE-NDA CMC VIDEOCONFERENCE
S	16-JUN-00	RESPONSE TO FDA FAX OF 07-JUN-00 (MYCOPHENYLATE AND SIROLIMUS DRUG INTERACTION STUDIES)
R	23-JUN-00	FDA FAX: FOLLOW UP COMMENTS TO CMC VIDEOCONFERENCE
S	23-JUN-00	CORRECTED PROTOCOL A1501011 (NOW INCLUDES APPENDIX F)
S	26-JUN-00	MONTHLY REPORT
R	28-JUN-00	FDA FAX: RESPONSE TO 6/16 CLINICAL PHARMACOLOGY SUBMISSION
S	28-JUN-00	GENERAL CORRESPONDENCE: RE FDA LETTER ON MYCOPHENOLATE, SIROLIMUS

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
R	29-JUN-00	REQUEST FOR 35 COPIES OF ADVISORY COMMITTEE BRIEFING DOCUMENT, NAMES OF SPEAKERS, TITLES OF PRESENTATIONS
S	06-JUL-00	CLIN PHARM PRE-MEETING PACKAGE (7/14 MEETING)
R	07-JUL-00	FDA FAX: COMMENT ON PROTOCOL A1501004
S	07-JUL-00	DRAFT PROTOCOL SYNOPSIS A1501021 (QTc STUDY)
S	10-JUL-00	AGE STRATIFICATION IN PROTOCOL A1501004 (SENT BY FAX 7/7)
S	11-JUL-00	PRE-NDA MEETING PACKAGE
S	12-JUL-00	RESPONSE TO FDA REQUEST FOR INFORMATION RE PEDIATRIC OPHTHAL TESTING
R	13-JUL-00	FDA FAX: MEETING ON JULY 14 2000
M	14-JUL-00	MEETING: CLINICAL PHARMACOLOGY AND MYCOLOGY TOPICS
S	21-JUL-00	MONTHLY REPORT
R	25-JUL-00	FDA FAX: JUNE 9, 2000 MEETING MINUTES (CARDIAC SAFETY)
S	25-JUL-00	DELAYED ENROLLMENT INTO PEDIATRIC PK STUDY
S	25-JUL-00	RESPONSE TO FDA FAX RECEIVED 6/23
M	26-JUL-00	PRE-NDA MEETING
S	31-JUL-00	TOXICOLOGY STUDY REPORTS
S	09-AUG-00	GENERAL CORRESPONDENCE: JULY 14, 2000 MEETING MINUTES AND OVERHEADS SHOWN

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	DATE	COMMENTS
R	14-AUG-00	FDA FAX: COMMENTS ON QT STUDY SYNOPSIS (A1501021)
S	15,16-AUG-00	MONTHLY REPORT
M	23-AUG-00	TELECON: FDA COMMENTS ON QT STUDY SYNOPSIS
S	07-SEP-00	MONTHLY REPORT
S	19-SEP-00	PROTOCOL A1501007 RATE OF RECRUITMENT (MULTIPLE DOSE PEDIATRIC PK STUDY)
S	20-SEP-00	DRAFT PROTOCOL A1501021 (QT STUDY)
R	22-SEP-00	FDA FAX: ASSIGNING USER FEE ID#3943
R	29-SEP-00	FDA COMMENTS FROM REVIEW OF PROTOCOL A1501021 (QT STUDY)
S	29-SEP-00	MONTHLY REPORT
S	29-SEP-00	REQUEST FOR DEFERRAL OF PEDIATRIC DATA
S	29-SEP-00	SAFETY REPORT: POSSIBLE INTERACTION BETWEEN VORICONAZOLE AND TERBINAFINE
S	05-OCT-00	RESPONSE TO FDA REQUEST: SAMPLE DRAFT ELECTRONIC DATA FOR TESTING PRIOR TO NDA SUBMISSION
S	06-OCT-00	PROTOCOL A1501007-9046 SITE SPECIFIC AMENDMENT
S	09-OCT-00	LETTER TO INVESTIGATORS RE POSSIBLE DRUG INTERACTION BETWEEN VORICONAZOLE AND SIROLIMUS
S	12-OCT-00	PROTOCOL A1501011 AMENDMENT
S	12-OCT-00	PRECLINICAL STUDY REPORTS

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	DATE	COMMENTS
S	19-OCT-00	MONTHLY REPORT
S	20-OCT-00	CARCINOGENICITY STUDY REPORTS 96018 & 96-96-31 SUBMITTED ON CD
S	20-OCT-00	POTENCY OF N-OXIDE METABOLITE
S	23-OCT-00	FINANCIAL DISCLOSURE INFORMATION
S	23-OCT-00	SAFETY REPORT: POSSIBLE MULTIPLE DRUG INTERACTION IN PATIENT ON VORI AND FIVE ANTIRETROVIRAL AGENTS
S	27-OCT-00	ANNUAL REPORT (JUN-00)
S	27-OCT-00	PROPOSAL FOR ISS SECTIONS
S	01-NOV-00	MONTHLY REPORT
R	02-NOV-00	FDA FAX: COMMENTS ON TIMING OF SUBMISSIONS DURING NDA REVIEW PERIOD
R	02-NOV-00	FDA FAX: RESPONSE TO SUBMISSIONS DATED SEPTEMBER 19,2000 AND SEPTEMBER 29,2000
S	02-NOV-00	SAFETY REPORT: POSSIBLE INTERACTION BETWEEN FENTANYL AND VORI
M	03-NOV-00	TELECON: CLOSURE OF STUDIES 307 AND 602
S	06-NOV-00	CITED MICROBIOLOGY REFERENCES
S	07-NOV-00	MONTHLY REPORT
S	08-NOV-00	602 STUDY CLOSURE
M	08-NOV-00	TELECON: FDA APPROVAL OF TRADENAME
S	09-NOV-00	PROPOSAL FOR INTEGRATED SUMMARY OF EFFICACY

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	DATE	COMMENTS
S	13-NOV-00	PRE-NDA MEETING MINUTES FOLLOW-UP DISCUSSION ON DOSING REGIMEN
S	17-NOV-00	ANTICIPATED TIMELINES FOR SUBMISSION OF SUPPLEMENTAL INFORMATION DURING THE NDA REVIEW PERIOD (FAX)
S	17-NOV-00	VFEND NDAs FILED FOR TABLETS AND I.V. FOR INJECTION (PFIZER COVER LETTERS DATE STAMPED RECEIVED FROM FDA)
R	20-NOV-00	FDA FAX: NOVEMBER 3,2000 TELECONFERENCE MINUTES
S	22-NOV-00	TOXICOLOGY STUDY REPORTS
S	22-NOV-00	ANOTHER DLT TAPE OF NDA SUBMITTED PER FDA REQUEST
S	29-NOV-00	SAFETY UPDATE PLANS
S	05-DEC-00	MONTHLY REPORT
R	11-DEC-00	REQUEST FROM DIVISION OF SCIENTIFIC INVESTIGATIONS FOR LIST OF INVESTIGATORS
S	15-DEC-00	REVISED TIMELINES FOR SUBMISSION OF SUPPLEMENTARY DATA
M	19-DEC-00	TELECON: POST NDA SUBMISSIONS
S	20-DEC-00	RESPONSE TO FDA REQUEST FOR INFORMATION (CARRERAS REQUEST)
M	21-DEC-00	TELECON: ISSUES AFTER 45-DAY INTERNAL FDA MEETING
S	22-DEC-00	INVESTIGATOR'S BROCHURE (DEC-2000) ADDENDUM
S	22-DEC-00	MONTHLY REPORT
R	09-JAN-01	REQUEST FROM BIOPHARM REVIEWER ON SPECIFIC PHASE 3 LOTS
S	15-JAN-01	NUMBER OF SUBJECTS IN SELECTED PHASE 3 STUDIES, BY SITE

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	DATE	COMMENTS
R	16-JAN-01	RECEIPT OF NDAs
S	17-JAN-01	MONTHLY REPORT
S	18-JAN-01	INFORMATION AMENDMENT: CLINICAL DATASETS
S	23-JAN-01	RATIONALE FOR STUDY CLOSURE 307/602
S	01-FEB-01	INFORMATION AMENDMENT: CLINICAL DATASETS
S	02-FEB-01	FAX RE SUSPENSION OF 1021 QT STUDY AFTER INFUSION-RELATED REACTIONS / REQUEST FOR TELECON
M	05-FEB-01	TELECON: INFUSION-RELATED REACTIONS
S	06-FEB-01	SAFETY REPORT: ANAPHYLACTOID REACTION IN TWO HEALTHY FEMALE SUBJECTS IN THE UK STUDY A1501021
R	07-FEB-01	REQUEST FOR LIST OF NON-US SITES (FROM DIVISION OF SCIENTIFIC INVESTIGATIONS)
S	07-FEB-01	OUTCOMES AND DISCONTINUATIONS OF NON-US SUBJECTS IN SELECTED PHASE 3 STUDIES BY SITE
M	08-FEB-01	TELECON: PEDIATRICS AND QT STUDY
R	09-FEB-01	REQUEST FOR PATHOLOGY SLIDES FROM RAT CARCINOGENICITY STUDY
S	09-FEB-01	MONTHLY REPORT
S	14-FEB-01	RESPONSE TO FDA REQUEST FOR INFORMATION QUERY 007
S	02-MAR-01	MONTHLY REPORT
S	02-MAR-01	RESPONSE TO QUERY 011 RE VISUAL AES; HISTOPATHOLOGICAL SECTIONS FROM DOG CARCINOGENICITY STUDY (ON CD-ROM)
S	07-MAR-01	MONTHLY REPORT

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	DATE	COMMENTS
S	14-MAR-01	FOUR-MONTH SAFETY UPDATE
S	20-MAR-01	MONTHLY REPORT
R	23-MAR-01	FDA APPROVAL OF REQUESTED DEFERRAL FOR PEDIATRIC STUDIES (REFERENCE: PFIZER CORRESPONDENCE OF 29-SEP-2000)
S	27-MAR-01	SAFETY REPORT: POSSIBLE DRUG INTERACTION BETWEEN VORICONAZOLE AND GLIPIZIDE
S	28-MAR-01	RESPONSE TO QUERY 015: SUMMARY OF THE INVESTIGATIONS INTO POSSIBLE CAUSATIVE FACTORS RELATED TO THE TWO OCCURANCES OF ANAPHYLACTOID REACTION IN STUDY A1501021
S	28-MAR-01	RESPONSE TO QUERY 020: LIST OF PATIENTS WHO WERE INCLUDED IN THE PER-PROTOCOL ANALYSIS AND SUSCEPTIBILITY DATA IF AVAILABLE
S	29-MAR-01	PRE-MEETING PACKAGE FOR TELECON ON QT
S	29-MAR-01	RESPONSE TO QUERY 016: WORD COPIES OF PROTOCOL 150-603; STUDY REPORT 150-603 TEST ONLY; INTEGRATED STUDIES TEXT ONLY
S	29-MAR-01	RESPONSE TO QUERY 018: TIMETABLE FOR SUBMISSION OF SUPPLEMENTAL INFORMATION
S	30-MAR-01	RESPONSE TO QUERY 014: PEDIATRIC EPIDEMIOLOGY DATA
S	02-APR-01	SAFETY REPORT: POSSIBLE DRUG INTERACTION BETWEEN VORICONAZOLE AND GATIFLOXACIN (TEQUIN)
S	02-APR-01	SAFETY REPORT: POSSIBLE DRUG INTERACTION BETWEEN VORICONAZOLE AND GATIFLOXACIN (TEQUIN)
M	02-APR-01	OPDRA RECOMMENDS AGAINST VFEND AS TRADENAME
S	03-APR-01	PATIENT PROFILES FOR STUDY 603
S	04-APR-01	PRE-MEETING CORRESPONDENCE RE A1501021

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	DATE	COMMENTS
M	04-APR-01	TELECON: QT STUDY AND TIMING OF SUBMISSION OF COMBINED ASPERGILLOSIS DATA
S	06-APR-01	FINAL REPORTS A1501014 AND A1501015
S	09-APR-01	RESPONSE TO QUERY 025: DRAFT DATA ON MORTALITY AND PRIMARY ANALYSIS DESCRIBED IN UMBRELLA PROTOCOL 307/602
S	11-APR-01	MONTHLY REPORT
S	12-APR-01	SAFETY REPORT: POSSIBLE DRUG INTERACTION BETWEEN VORI AND VENLAFAXINE
S	12-APR-01	PROTOCOL 608 AMENDMENT
S	16-APR-01	STUDY REPORTS: A1501007, A1501011, A1501016
R	16-APR-01	FDA MINUTES OF 2/5/01 TELECON ON INFUSION-RELATED REACTIONS
S	01-MAY-01	PRE-MEETING PACKAGE FOR 5/3 TELECON ON REGULATORY ISSUES
S	01-MAY-01	MONTHLY REPORT
S	02-MAY-01	RESPONSE TO QUERY 028: CRFS/PIDS
S	02-MAY-01	PRE-TELECON PACKAGE: INFUSION-RELATED REACTIONS IN QT STUDY 1027 (REPLACEMENT STUDY FOR 1021)
M	03-MAY-01	TELECON: QTc STUDY, NDA REVIEW, OTHER TOPICS
S	08-MAY-01	SAFETY REPORT: FOLLOW UP TO THE APRIL 12, 2001 SAFETY REPORT
S	10-MAY-01	CD-ROM CONTAINING TABLES, FIGURES AND DATASETS FROM THE UMBRELLA ANALYSIS - PROMISED IN THE 4/9/01 SUBMISSION
S	15-MAY-01	RESPONSE TO QUERY 034: CASE REPORT FORMS FOR SEVEN PATIENTS WITH INFECTIONS DUE TO RARE FUNGAL PATHOGENS
M	15-MAY-01	TELECON: INSPECTION OF RINGASKIDDY MANUFACTURING SITE

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	DATE	COMMENTS
S	16-MAY-01	RESP: 150-1004
S	16-MAY-01	RESPONSE TO QUERY 033: ELECTRONIC COPY OF MAY 25,2001 MEETING INFORMATION
S	17-MAY-01	MONTHLY REPORT
S	17-MAY-01	RESPONSE TO QUERY 031: ABSTRACT ABOUT THE UMBRELLA ASPERGILLOSIS TRIAL PREPARED FOR THE SEPTEMBER ICAAC MEETING
S	17-MAY-01	RESPONSE TO QUERY 036: DATABASE CLOSURE DATES
S	18-MAY-01	PRE-MEETING CORRESPONDENCE: AGENDA/ATTENDEES
S	18-MAY-01	ARCHIVE COPY OF STUDY REPORT SYNOPSIS 150-1004
S	18-MAY-01	RESPONSE TO QUERY 037: EMPIRICAL THERAPY PROTOCOL (603) INFORMATION
R	22-MAY-01	REQUEST FOR QT DATA FOR 5/25 MEETING
M	25-MAY-01	MEETING: CARDIAC SAFETY AND ASPERGILLOSIS DATA
S	31-MAY-01	CD ROM CONTAINING INFORMATION REGARDNG PATIENTS WITH FUNGAL INFECTIONS DUE TO RARE PATHOGENS
S	04-JUN-01	MANUSCRIPT REPORTING THE RESULTS OF STUDY 150-305
S	04-JUN-01	CD ROM CONTAINING A LIST OF PATIENTS WITH FUNGAL INFECTIONS DUE TO RARE PATHOGENS WHO HAVE CULTURE REPORTS
R	04,05,07,08-JUN-01	QUESTIONS FROM MEDICAL REVIEWER
S	05-JUN-01	PROTOCOL 1010 AMENDMENT
S	05-JUN-01	FOLLOW-UP TO RESPONSE OF 05/31/01 - CD ROM CONTAINING ADDITIONAL INFORMATION REGARDING PRIOR ANTIFUNGAL THERAPY
S	07-JUN-01	RESPONSE TO QUERY 041: SUBJECTS WITH MISSING GLOBAL OR MYCOLOGICAL

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	DATE	COMMENTS
		RESPONSES
S	12-JUN-01	TABLE OF CONTENTS FOR JUNE 2001 NDA AMENDMENT; DETAILS OF AMENDMENT
R	12-JUN-01	REQUEST FROM BIOPHARM REVIEWER
S	12-JUN-01	RESPONSE TO QUERY 044: PROVIDED MISSING DATA TO COMPLETE TABLES OF EVALUABLE ISOLATES AND EVALUABLE SUBJECTS AND OUTCOME IN EVALUABLE ISOLATES AND EVALUABLE SUBJECTS
M	12-JUNE-01	TELECON: TIMEFRAME FOR RESPONSE TO FDA QUERIES; NAMES OF DIRECT PFIZER CONTACTS
S	13-JUN-01	MONTHLY REPORT
R	14-JUN-01	REQUEST FOR CMC DATA; QUESTIONS FROM MEDICAL REVIEWER
M	14-JUN-01	TELECON: VFEND AS TRADENAME
R	15--JUN-01	REQUEST FOR IN VITRO DISSOLUTION DATA
S	19-JUN-01	RESPONSE TO QUERY 045: DEMOGRAPHICS TABLE
M	19-JUN-01	TELECON: DISSOLUTION DATA
S	21-JUN-01	NDA AMENDMENT: STUDY REPORTS FOR 307/602 (ASPERGILLOSIS UMBRELLA ANALYSIS) / CLIN PHARM STUDIES A1501004, A1501011, A1501024 / ISS UPDATE / REVISED USPI
S	21-JUN-01	RESPONSE TO RESPONSE TO FDA REQUEST FOR INFORMATION - 603 PUBLICATION
S	21-JUN-01	RESPONSE TO QUERY 032 NUMBER OF SUBJECTS IN PROTOCOL 307/602, BY SITE
R	25-JUN-01	LOCATION OF ADVISORY COMMITTEE MEETING
R	25-JUN-01	REQUEST FOR DISSOLUTION TESTING
R	26-JUN-01	QUERIES FROM MEDICAL AND BIOSTATS REVIEWERS
S	27-JUN-01	GENERAL CORRESPONDENCE: TRADENAME VFEND AND BACKUP AZAVOR

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BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE REGULATORY REVIEW PERIOD FOR VFEND® (VORICONAZOLE) TABLETS

	DATE	COMMENTS
S	27-JUN-01	RESPONSE TO QUERY 048 FULL DISSOLUTION PROFILES FOR VORI FORMULATIONS N6117 AND N8175 IN PH 4.5 AND PH 6.8 BUFFERS
R	28-JUN-01	DEADLINES FOR ADVISORY COMMITTEE MEETING BRIEFING DOCUMENT
S	28-JUN-01	RESPONSE TO QUERY 056 TABULATED DATA ON CLINICAL TRIAL LOTS AND STABILITY BATCHES
R	29-JUN-01	FDA FAX: PREPARATION FOR THE UPCOMING ANTIVIRAL DRUGS ADVISORY COMMITTEE ON OCTOBER 4 2001
S	29-JUN-01	RESPONSE TO QUERY 053/054: CD-ROM CONTAINING REQUESTED DATASETS AND HARD COPY BRIEF CASE SYNOPSES OF NINE NEW SUBJECTS IN STUDIES 150-309/604
R	06-JUL-01	FDA FAX: REQUEST FOR CLARIFICATION ON 304 DATASETS
S	09-JUL-01	RESPONSE TO QUERY 065: ELECTRONIC SECTION OF 13 OF 307/602 STUDY REPORT; EXACT ABSOLUTE NEUTROPHIL COUNTS FOR EACH PATIENT IN 307/602; CLARIFICATION OF THE STANDARDIZATION AND NORMALIZATION PROCESS FOR LAB TEST VALUES
S	10-JUL-01	MONTHLY REPORT
S	13-JUL-01	SAFETY REPORT: POSSIBLE INTERACTION BETWEEN VORICONAZOLE AND CODEINE
S	13-JUL-01	RESPONSE TO QUERY 066: CLARIFICATION ON VARIABLES AND LABELS IN STUDY 304 DATASETS
S	16-JUL-01	RESPONSE TO QUERY 069 - LIVER BIOPSY REPORT FOR PATIENT 304 0025 0736
S	17-JUL-01	RESPONSE TO QUERY 067: STUDY 1024
S	18-JUL-01	FOLLOW-UP TO RESPONSE TO QUERY 066: VARIABLE NAMES AND CORRECT DATASETS
S	19-JUL-01	RESPONSE TO QUERY 070: REQUEST FOR MEASURING ITRACONAZOLE LEVELS IN PARACOCCI STUDY
S	20-JUL-01	PROPOSED PEDIATRIC STUDY REQUEST
S	20-JUL-01	RESPONSE TO QUERY 066: FOLLOW-UP WITH SPREADSHEET IDENTIFYING

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	DATE	COMMENTS
		CLARIFICATIONS AND CORRECTIONS TO DATASETS
S	24-JUL-01	PROTOCOL 150-606 AMENDMENT
S	24-JUL-01	RESPONSE TO QUERY 067: FOLLOW UP A1501024 BIODYNAMICS AND ABC ANALYTICAL REPORTS
S	24-JUL-01	RESPONSE TO QUERY 073: SUSCEPTIBILITY DATA FOR PTS IN ALLMO DATASET
S	24-JUL-01	RESPONSE TO QUERY 074: DATA LISTINGS FOR 307/602
S	25-JUL-01	RESPONSE TO QUERY 072: REGARDING EXPERT ASSESSMENTS FOR 307,307/602
S	30-JUL-01	IMPORT NOTIFICATION
S	31-JUL-01	RESPONSE TO QUERY 075: REGARDING VORICONAZOLE DRUG SUBSTANCE AND VORICONAZOLE DRUG PRODUCT (TABLET)
S	01-AUG-01	MONTHLY REPORT
S	08-AUG-01	TRADENAME SUPPORT
S	10-AUG-01	DRAFT BRIEFING DOCUMENT FOR ADVISORY COMMITTEE MTG (REQUEST FOR REVIEW)
S	13-AUG-01	SAFETY REPORT: RIGHT BUNDLE BRANCH BLOCK
S	22-AUG-01	RESPONSE TO QUERY 089: CD-ROM CONTAINING INVASIVE CANDIDIASIS AND ESOPHAGEAL CANDIDIASIS DATASETS
S	22-AUG-01	RESPONSE TO QUERY 092: OLAT DOSE AND DURATION FOR SUBJECTS RANDOMIZED TO AMPHOTERICIN B REGIMEN
S	24-AUG-01	MONTHLY REPORT
R	24-AUG-01	FDA FAX: RECOMMENDATIONS TO THE SPONSOR'S ADVISORY COMMITTEE BRIEFING DOCUMENT

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	DATE	COMMENTS
S	24-AUG-01	RESPONSE TO FDA QUERY 081/082: LIVER DATA TABLES; UPDATED TABLE 4 FROM ORIG NDA ISS SECTION 11.1;LIVER BIOPSY INFO; RASH BIPOSY INFO
S	27-AUG-01	CMC - VORI TABLET DEBOSSING CHANGES
S	30-AUG-01	UPDATED DATASETS
S	31-AUG-01	FINAL BRIEFING DOCUMENT FOR ANTIVIRAL ADVISORY COMMITTEE MEETING 10/4
S	31-AUG-01	RESPONSE TO QUERY 097: CD-ROM CONTAINING DATA FOR MITT POPULATION IN STUDIES 150-602/307
S	31-AUG-01	RESPONSE TO QUERY 099: CONTAINING UPDATED STABILITY DATA FROM THE RECENT CHECKPOINTS OF THE STABILITY REGISTRATION PROGRAM
S	04-SEP-01	RESPONSE TO QUERY 081/082 FOLLOW UP: ADDITIONAL DATA ON THE ADVERSE EVENTS WHICH CODED TO RASH.
S	04-SEP-01	RESPONSE TO QUERY 086: LIVER TEST DATA BROKEN OUT BY STUDY
S	05-SEP-01	RESPONSE TO QUERY 096: MIC DATA FOR PATIENT 608 50650044
S	05-SEP-01	RESPONSE TO QUERY 100: CD-ROM CONTAINING REQUESTED DATA ON 22 NEW PATIENTS FROM RECENTLY COMPLETED RARE/REFACTORY STUDIES 309 AND 604
S	05-SEP-01	RESPONSE TO QUERY 102: TOTAL ENROLLMENT BY CENTER AND THE ENROLLMENT NUMBERS IN SPECIFIC SUBPOPULATIONS BY CENTER IN STUDY 150-603
S	05-SEP-01	RESPONSE TO QUERY 106: CD-ROM CONTAINING DATASET FOR ADDITIONAL DATA FOR PATIENTS IN STUDY 150-603
S	05-SEP-01	RESPONSE TO QUERY 107: CD-ROM CONTAINING DATASETS
S	06-SEP-01	RESPONSE TO QUERY 094: SUMMARY SUPPORTING THE USE OF VORICONAZOLE FOR THE TREATMENT OF PATIENTS WITH INVASIVE CANDIDA INFECTIONS WHO ARE REFRACTORY TO OTHER THERAPY
S	07-SEP-01	QT DUE DILIGENCE REPORT
S	07-SEP-01	RESPONSE TO QUERY 104: CD-ROM CONTAINING CRFS AND DATASETS

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	DATE	COMMENTS
S	13-SEP-01	RESPONSE TO QUERY: ALL PEDIATRIC DATA
R	14-SEP-01	FDA FAX - FDA BACKGROUND PACKAGE FOR ADVISORY COMMITTEE
S	19-SEP-01	RESPONSE TO QUERY 105: DATA TABLES AND GRAPHS WHICH SHOW THE MIC DATA FOR THE MITT POPULATION
S	19-SEP-01	RESPONSE TO QUERY 108: DATA ON FLUCONAZOLE RESISTANT FUNGAL STRAINS AND FLUCONAZOLE SUSCEPTIBLE FUNGAL STRAINS
S	19-SEP-01	RESPONSE TO QUERY 110: HEPATIC EXPERT PANEL MEETING MINUTES; INDIVIDUAL PATIENT DETAILS FOR THE CASES DISCUSSED
S	19-SEP-01	RESPONSE TO QUERY 111: AVAILABLE DATA ON NINE PATIENTS GIVEN VORI EITHER AS EYE DROPS, INTRAVITREALLY, OR FOR SINUS IRRIGATION
S	20-SEP-01	MONTHLY REPORT
S	26-SEP-01	ANNUAL REPORT
S	26-SEP-01	RESPONSE TO QUERY 114: CONTAINING CIOMS REPORT FOR PT 1025-2297-1; CD-ROM CONTAINING CRFS
S	26-SEP-01	RESPONSE TO QUERY 117: CD-ROM CONTAINING DATASETS INCLUDED IN A 16-APR-01 SUBMISSION
S	27-SEP-01	RESPONSE TO QUERY 112: CONTAINING MIC AND MFC DATA FOR STUDIES 602 AND 604
M	28-SEP-01	PRE-ADVISORY COMMITTEE MEETING
S	02-OCT-01	RESPONSE TO QUERY 118: CONTAINING 603 DEATH NARRATIVES
S	03-OCT-01	RESPONSE TO QUERY 113: CD-R0M CONTAINING PEDIATRIC DATA
M	04-OCT-01	PRESENTATION TO ANTIVIRAL ADVISORY COMMITTEE: ASPERGILLOSIS AND EMPIRICAL THERAPY
M	12-OCT-01	TELECON: REQUEST FOR MEETING ON TRADENAME FDA REQUESTS FOR DATA ON PATIENT WITH HEPATIC REACTION / STUDIES USING IV

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	DATE	COMMENTS
		SUPPLIES FROM CATALYTICA
S	15-OCT-01	SAFETY REPORT: POSSIBLE DRUG INTERACTION BETWEEN VORICONAZOLE AND RIFAMYCIN
R	16-OCT-01	FDA FAX: DIVISION'S COMMENTS ON PROTOCOL 150-606
M	16-OCT-01	TELECON: DIVISION'S APPROVAL OF VFEND TRADENAME; TARGET ACTION DATE 11/16/01
S	17-OCT-01	LETTER CONFIRMING APPROVAL OF TRADENAME (AS DISCUSSED DURING 10/16 TELECON)
S	18-OCT-01	MONTHLY REPORT
S	23-OCT-01	BUTANE SULTONE (COMMENTS FROM EUROPEAN REGULATORS)
S	23-OCT-01	REVISED PROPOSED USPI
S	23-OCT-01	RESPONSE TO QUERY 120: ADDITIONAL INFORMATION AVAILABLE REGARDING PATIENT 309 0137 1401
S	23-OCT-01	RESPONSE TO QUERY 123: INDIVIDUAL TABLET DATA
S	24-OCT-01	RESPONSE TO QUERY 125: CMC INFORMATION REQUESTED IN 10/17 FAX FROM FDA
S	23-OCT-01	REVISED PROPOSED LABEL (CHANGES FROM DISCUSSION DURING ADVISORY COMMITTEE MEETING)
S	30-OCT-01	SAFETY REPORT: POSSIBLE DRUG INTERACTION BETWEEN VORICONAZOLE AND CYCLOSPORINE AND/OR BROTIZOLAM
S	31-OCT-01	RESPONSE TO QUERY 121: CD-ROM CONTAINING INDIVIDUAL ESTIMATES OF ABSOLUTE BIOAVAILABILITY OF VORICONAZOLE
S	05-NOV-01	SAFETY REPORT: DEATH DUE TO PANCREATITIS AND RENAL DYSFUNCTION
S	05-NOV-01	RESPONSE TO QUERY 113: FOLLOW-UP PAPER AND CD-ROM CONTAINING VISUAL SAFETY, LABORATORY TESTS, AND ADVERSE EVENTS IN THE PEDIATRIC POPULATION AND CRFS

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	DATE	COMMENTS
S	05-NOV-01	SAFETY REPORT: DEATH DUE TO PANCREATITIS AND RENAL DYSFUNCTION
M	07, 08, 09-NOV-01	USER FEE GOALS AND ACTION DATES
S	08-NOV-01	RESPONSE TO QUERY 125: FOLLOW-UP CONTAINING PROPOSED CHANGES TO THE LABEL REGARDING THE RECOMMENDED RANGE OF DILUENT VOLUME TO BE USED
S	09-NOV-01	BACKUP SLIDES SHOWN AT ADVISORY COMMITTEE MEETING
S	14-NOV-01	MONTHLY REPORT
S	14-NOV-01	BRIEFING DOCUMENT ERRATA
S	20-NOV-01	RESPONSE TO QUERY 121: FOLLOW-UP CONTAINING REQUESTED DATA IN A SAS TRANSPORT FILE
S	28-NOV-01	RESPONSE TO QUERY 128: CD CONTAINING DATA FOR PEDIATRIC PATIENTS
R	16-NOV-01	USER FEE GOAL DATE REGARDING MAJOR AMENDMENTSUBMITTED 13-NOV-2001 NEW USER FEE GOAL DATE: DECEMBER 17, 2001
S	30-NOV-01	RESPONSE TO QUERY 120: FOLLOW-UP CONTAINING INFORMATION FROM AN INDEPENDENT HEPATOLOGIST ON LIVER BIOPSY SLIDES OF PATIENT 309 1371407
S	03-DEC-01	SAFETY REPORT: FOLLOW-UP FOR OCTOBER 30, 2001 SAFETY REPORT
M	04-DEC-01	TELECON: DRAFT WRITTEN REQUEST TO BE PRESENTED TO PEDIATRIC IMPLEMENATION TEAM
S	05-DEC-01	MONTHLY REPORT
M	07-DEC-01	TELECON: PRECLINICAL SECTIONS OF LABEL
S	10-DEC-01	RESPONSE TO QUERY 120: LIVER BIOPSY SLIDES ON CD
S	10-DEC-01	RESPONSE TO QUERY 129: MARKETING APPLICATIONS SUBMITTED WORLDWIDE

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	DATE	COMMENTS
S	11-DEC-01	FINAL STUDY REPORT A1501024 (RIFABUTIN INTERACTION)
M	11-DEC-01	ACTION LETTERS TO BE SENT BY FDA
R	17-DEC-01	APPROVABLE LETTER FOR INFECTIONS DUE TO ASPERGILLUS AND SCEDOSPORIUM AND FUSARIUM SPECIES APPROVABLE LETTER FOR ESOPHAGEAL CANDIDIASIS (FDA assigned temporary NDA numbers 21-464 and 21-466) NON-APPROVABLE LETTER FOR EMPIRICAL THERAPY (FDA assigned temporary NDA numbers 21-465 and 21-467) FDA COMMENTS ON LABEL
S	17-DEC-01	PROPOSED CHANGE IN VALIDATION PLAN FOR ORAL TABLETS (letter to District Office)
S	17-DEC-01	PROPOSED DOSES FOR QTC STUDY USING ORAL VFEND
S	19-DEC-01	PFIZER COMMENTS ON DRAFT WRITTEN REQUEST
S	20-DEC-01	MONTHLY LETTER
R	21-DEC-01	FDA FAX: FORMAL WRITTEN REQUEST FOR PEDIATRIC STUDIES
S	21-DEC-01	RESPONSE TO DECEMBER 17, 2001 ACTION LETTERS - REQUEST FOR MEETING (FDA ASSIGNED TEMPORARY NDA NUMBERS 21-464/21-466)
S	26-DEC-02	APPROVAL FROM DISTRICT OFFICE OF PROPOSED CHANGE IN VALIDATION PLAN FOR ORAL TABLETS
R	02-JAN-02	FDA REPLY TO REQUEST TO MODIFY ORIGINALLY PRESENTED VALIDATION PLAN FOR VFEND (VORICONAZOLE) TABLETS
S	11-JAN-02	MONTHLY REPORT
S	11-JAN-02	LETTER TO DISTRICT OFFICE CONFIRMING RECEIPT OF APPROVAL OF THE CONCURRENT VALIDATION APPROACH FOR THE 50 MG TABLETS; AGREEMENT TO

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	DATE	COMMENTS
		NOTIFY FDA PRIOR TO MARKETING
S	14-JAN-02	DRAFT PROTOCOL A1501041
R	16-JAN-02	FDA FAX: COMMENTS REGARDING QTC STUDY
S	22-JAN-02	CMC AMENDMENT: AMENDED DFM 80120a
S	28-JAN-02	CMC AMENDMENT
S	31-JAN-02	REQUEST FOR EXTENSION OF DEFERRAL FOR PEDIATRIC DATA
S	01-FEB-02	MONTHLY REPORT
S	19-FEB-02	SAFETY REPORT: HEMORRHAGIC COLITIS, ENTEROCOLITIS, SEPTIC SHOCK
S	21-FEB-02	PRE-MEETING CORRESPONDENCE: INDICATIONS TO BE INCLUDED IN LABEL
S	22-FEB-02	MONTHLY REPORT
S	25-FEB-02	PRE-MEETING CORRESPONDENCE: PROPOSED REVISIONS TO LABEL
S	25-FEB-02	FINAL PROTOCOL A1501041
S	28-FEB-02	PRE-MEETING CORRESPONDENCE: SLIDES PRESENTATION FOR FDA MEETING MARCH 4 2002
M	04-MAR-02	TELECON: INDICATIONS SECTION OF THE LABEL
R	13-MAR-02	FDA FAX: COMMENTS ON CLIN PHARM SECTION OF LABEL – FOR TELECON ON 3/14/02
S	14-MAR-02	SAFETY REPORT: POSSIBLE TORSADES DE POINTES
M	14-MAR-02	TELECON: LABELING DISCUSSION (CLIN PHARM SECTION)

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	DATE	COMMENTS
S	21-MAR-02	MONTHLY REPORT
S	26-MAR-02	NDA RESUBMISSION: COMPLETE RESPONSE TO APPROVABLE LETTER
R	28-MAR-02	EXTENSION OF DEFERRAL DATE TO 12/31/03 FOR PEDIATRIC ORAL FORMULATION
S	05-APR-02	NDA TRANSFER NOTIFICATION – OWNERSHIP TO CPPI
S	08-APR-02	CPPI NDA TRANSFER OF NOTIFICATION, RIGHT OF IND REFERENCE
S	16-APR-02	MONTHLY REPORT
S	19-APR-02	PROTOCOL A1501010 AMENDMENT
S	19-APR-02	PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES
S	24-APR-02	SAFETY REPORT: DYSTHROIDEA
R	29-APR-02	FDA LETTER: NOTIFICATION OF CLINICAL TRIALS DATA BANK AVAILABILITY TO PUBLIC
R	29-APR-02	FDA FAX: LABELING COMMENTS
R	29-APR-02	FDA LETTER: ACKNOWLEDGEMENT OF 26-MAR-02 NDA RESUBMISSION USER FEE GOAL DATE 24-MAY-02
S	02-MAY-02	MONTHLY REPORT
S	02-MAY-02	RESPONSE: QUERY 132: PK DATASET FOR ADOLESCENT TO ADULT COMPARISON
S	03-MAY-02	SAFETY REPORT: POSSIBLE DRUG INTERACTION BETWEEN SIMVASTATIN AND VORICONAZOLE
R	03-MAY-02	FDA FAX: LABELING COMMENTS

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	DATE	COMMENTS
M	03, 06, 14, 15-MAY-02	TELECONS TO DISCUSS LABELING
R	10-MAY-02	FDA FAX: LABELING COMMENTS
S	21-MAY-02	PROPOSED US PACKAGE INSERT
S	23-MAY-02	DATES FOR PHASE 4 STUDIES (PER FDA REQUEST; TO BE INCLUDED IN APPROVAL LETTER)
S	23-MAY-02	PROPOSED US PACKAGE INSERT (FINAL CHANGES)
S	24-MAY-02	INVESTIGATOR'S BROCHURE (MAY-02)
S	24-MAY-02	MONTHLY REPORT
R	24-MAY-02	APPROVAL LETTER AND AGREED LABEL FOR VFEND TABLETS AND I.V.

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